IN THE UNITED STATED DISTRICT COURT FOR THE EASTERN DISTRICT OF TENNESSEE, AT KNOXVILLE

JOE KITCHENS Plaintiff, v. DEPUY ORTHOPAEDICS, INC.; DEPUY, INC.; DEPUY INTERNATIONAL LIMITED; JOHNSON & JOHNSON; JOHNSON & JOHNSON SERVICES, INC.; and JOHNSON & JOHNSON INTERNATIONAL, Defendants.	)	Civ. No. 3:15-cv-396 JURY DEMAND

COMPLAINT

Comes the Plaintiff, by and through counsel, and for a cause of action against Defendants would state as follows:

I. PARTIES

1. Joe Kitchens ("Plaintiff") is, and at all times relevant to this Complaint was, a citizen and resident of Tennessee.

2. DePuy, Inc., by information and belief, is, and at all times relevant to this Complaint was, an Indiana corporation with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581, and does business in and/or having directed its activities in the State of Tennessee, including willfully advertising and selling and delivering the product at issue in Tennessee. DePuy, Inc., upon information and belief, changed its name to DePuy Orthopaedics, Inc. in or around 1992. In any event, DePuy, Inc. may be served with process through its registered agent

for service of process: CT Corporation System, 800 S. Gay St., Ste. 2021, Knoxville, TN 37929.

3. DePuy Orthopaedics, Inc., by information and belief, is, and at all times relevant to this Complaint was, an Indiana corporation with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581, and does business in and/or having directed its activities in the State of Tennessee, including willfully advertising and selling and delivering the product at issue in Tennessee. DePuy Orthopaedics, Inc. may be served with process through its registered agent for service of process: CT Corporation System, 800 S. Gay St., Ste. 2021, Knoxville, TN 37929.

4. DePuy International Limited, by information and belief, is, and at all times relevant to this Complaint was, a corporation organized and existing pursuant to the laws of the United Kingdom, with its principal place of business located at Number One, White Rose Office Park, Millshaw Park Lane, Leeds LS11 0BG. DePuy International Limited may be served with process through the office of the United States Secretary of State.

5. DePuy Orthopaedics, Inc., DePuy, Inc., and DePuy International Limited are hereinafter collectively referred to as "DePuy."

6. Johnson & Johnson, Inc., Johnson & Johnson Services, Inc., and Johnson & Johnson International (hereinafter collectively referred to as "Johnson & Johnson"), by information and belief, is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principle place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and does business in and/or having directed its activities

in the State of Tennessee and, including willfully advertising and selling and delivering the product at issue in Tennessee. Johnson & Johnson, Inc. may be served with process pursuant to Tennessee's long arm statute through the Tennessee Secretary of State.

7. At all times relevant to this Complaint, Defendants were the agents of each other, and in doing the things alleged herein, each defendant was acting within the course and scope of its agency and was subject to and under the supervision and control of its co-defendants.

8. Alternatively, at all times relevant to this Complaint, Defendants were joint venturers in the design, development, manufacture, distribution, sales, and marketing of Pinnacle hip implant devices, and in doing the things alleged herein, each defendant was acting in furtherance of the joint venture and on behalf of all other defendants.

9. At all times relevant to this Complaint, Defendants acted in concert with each other, in furtherance of a common plan or design, with respect to the conduct alleged herein, and each is responsible for the tortious conduct of the other.

II. JURISDICTION AND VENUE

10. This court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the parties are citizens of different states and the amount in controversy far exceeds $75,000, exclusive of interests and costs.

11. Venue is proper in the Eastern District of Tennessee, pursuant to 28 U.S.C. § 1391(a)(2), because the events giving rise to these claims occurred within this district.

III. BACKGROUND

12. Defendants developed, designed, tested, manufactured, distributed, and sold the Pinnacle Acetabular Cup System ("Pinnacle device"), which is a hip bearing system to be used in a total hip replacement or revision surgery. The Pinnacle device system includes two component parts: the liner and acetabular cup. Defendants developed, designed, tested, manufactured, and distributed at least four different acetabular cups and three different liners to be used as the Pinnacle device. The acetabulum cup is comprised of titanium metal on its outer shell and can be fixed to the bone with screws or without screws by growing into the bone with Defendants Gripton™ technology. The Pinnacle device has three different liners to choose from made of cobalt-chromium metal, polyethylene plastic or ceramic. One of the cobalt-chromium metal liners is the Ultamet® XL.

13. The Pinnacle device is critically different than most hip replacement devices because a metal acetabular liner may be used instead of a polyethylene plastic acetabular liner. The Pinnacle device with a metal liner, such as the Ultamet® XL, is a "metal-on-metal" device due to the fact that both articulating surfaces – the femoral head (ball) and acetabulum liner (socket) – are comprised of cobalt-chromium (CoCr) metal. Therefore, the metal-on-metal design forces metal to rub against metal with the full weight and pressure of the human body creating metallic debris to be released into the Plaintiff's hip socket and blood stream. Because of Defendants' defective design for the Pinnacle device, hundreds of patients – including Plaintiff – have been forced to undergo surgeries to replace the failed hip implants.

14. Defendants describe the Pinnacle device as "the only product available that provides the option of choosing a polyethylene or metal insert for use with the same outer titanium cup that replaced the socket of the natural hip."

15. Defendants developed, designed, tested, manufactured, and distributed the metal and ceramic femoral heads that are used with the Pinnacle device that directly contact the liner. The Articul/eze-M Spec Femoral Head and the aSphere M-Spec Femoral Head are metal femoral heads commonly used with the Pinnacle device.

16. The Pinnacle device is fully compatible with DePuy's complete line of advanced femoral stems that Defendants develop, design, test, manufacture, and distribute such as the AML®, Prodigy®, Summit™, Corail®, Tri-Lock®, and S-ROM femoral stems and sleeves.

17. The Pinnacle device is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

18. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle device, to undergo premarket approval by the FDA. Premarket approval is a process that obligates the manufacturer to design and implement a clinical investigation and submit the results of the investigations to the FDA.

19. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that

have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties, and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

20. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

21. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – was not required to undergo premarket approval.

22. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a pre-MDA device (i.e., a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA at least 90 days prior to the device's introduction on the market of the manufacture's intent to market a device, and to explain the device's substantial equivalence to pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

23. The MDA does not require an FDA determination that the device is in fact substantially equivalent to a grandfathered device.

24. Instead of assuring the safety of the Pinnacle device through clinical trials, Defendants sought to market the Pinnacle device, without conducting any clinical trials by obtaining FDA approval under section 510(k). To that end, Defendants submitted a section 510(k) premarket notification of intent to market the Pinnacle device.

25. By telling the FDA that the Pinnacle device's design was "substantially equivalent" to other hip components and products on the market, Defendants were able to avoid the safety review required for premarket approval under FDA regulations, which includes clinical trials.

26. The FDA cleared the Pinnacle device for sale by means of the abbreviated 510(k) process, and consequently, the FDA did not require the Pinnacle device to undergo clinical trials.

27. The 510(k) notification for the Pinnacle device includes Defendants' assertion that it believes the Pinnacle device to be substantially equivalent to grandfathered devices – devices that were never required to be reviewed for safety and effectiveness.

28. Significantly, unlike the premarket approval process, the 510(k) notification process does not call for scrutiny – or even clinical testing – of a device's safety and effectiveness.

29. A finding of substantial equivalence is not equivalent to a finding of a device's safety and effectiveness.

30. Thus, the FDA's finding of "substantial equivalence" had nothing to do with reviewing the Pinnacle device's safety and effectiveness but rather only a

determination of equivalence to grandfathered devices that never underwent safety and effectiveness review.

31. Defendant sold approximately 150,000 Pinnacle devices.

32. Because the Defendants brought the Pinnacle devices to market through the 510(k) process rather than the rigorous PMA process, they are not entitled to dismissal by way of federal pre-emption of Plaintiff's state law claims under existing case law precedent.

IV. FACTUAL ALLEGATIONS

33. DePuy is a fully owned subsidiary of Johnson & Johnson.

34. DePuy and Johnson & Johnson design, develop, manufacture, and distribute hip implant devices in order to reconstruct human hip joints that are diseased due to conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis, or fracture. The hip joint connects the femur bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

35. Specifically, DePuy and Johnson & Johnson designed, developed, manufactured, and distributed the Pinnacle device, including DePuy Pinnacle 100 Acetabular Cup, Lot Number BE1E81000; the DePuy Summit Tapered Hip Stem with Porocoat, Lot Number 2363940; and DePuy Articul/eze M Metal Femoral Head, Lot Number BE9CG1000.

36. DePuy and Johnson & Johnson have, at all times relevant, controlled the design, development, and manufacture of the Pinnacle device.

37. DePuy and Johnson & Johnson have, at all times relevant, controlled the distribution, marketing, and sales of the Pinnacle devices in Tennessee. Defendants represented to patients like Plaintiff that the Pinnacle device was a safe and durable hip implant device that would outlast previous plastic models.

38. Contrary to the Defendants marketing campaigns, Defendants have known, or should have known, that the Pinnacle device was not safe or durable and presented a considerable risk of injury to those implanted with it.

39. Defendants knew, or should have known, of reports that metal-on-metal implants, such as the Pinnacle device, could experience unusual, premature, or increased friction and/or wear and tear, and that such wear and tear could damage surrounding tissues and/or cause premature failure of the implant.

40. Defendants knew, or should have known, of reports that metal-on-metal implants, such as the Pinnacle device, generated unusually high amounts of metal debris over time due to the unusual, premature or increased friction and/or wear and tear. This debris can spread throughout the surrounding bone and tissue and cause serious complications and damage, including possible development of ALVAL (*a*septic *l*ymphocyte-dominated *v*asculitis-associated *l*esion).

41. The Pinnacle device is constructed of metal alloys containing cobalt and chromium.

42. Large amounts of metal debris in a person's system can cause metallosis. Metallosis, as a result of cobalt poisoning, has been linked to hearing loss, pain, rashes, diminished cognitive function, memory loss, anxiety, headaches, mental fog, breathlessness, dizziness, tissue necrosis, metal staining, pseudotumors, and other medical conditions. Increased cobalt and chromium have been linked to cancer in laboratory animals. According to the International Agency on Cancer, cobalt is a probable human carcinogen.

43. Notwithstanding these risks, DePuy and Johnson & Johnson did not halt the sale of the Pinnacle device even as studies began to reveal the metal-on-metal implants, such as the Pinnacle device, are potentially dangerous because they can deposit large amounts of metal debris into the patient's body as the device wears. This results in the patient requiring revision surgery much sooner than the industry expectation.

44. On information and belief, DePuy and Johnson & Johnson marketed the Pinnacle devices to Dr. Matthew Nadaud ("Dr. Nadaud") in Tennessee, in the manner described above. Subsequently, the Defendants trained and instructed Dr. Nadaud in the use of the implantation of the devices.

45. Sometime prior to May 2007, DePuy and Johnson & Johnson manufactured DePuy Pinnacle 100 Acetabular Cup, Lot Number BE1E81000; the DePuy Summit Tapered Hip Stem with Porocoat, Lot Number 2363940; and DePuy Articul/eze M Metal Femoral Head, Lot Number BE9CG1000.

46. Dr. Nadaud implanted the Pinnacle device into Plaintiff's right hip on May 9, 2007.

47. On information and belief, due to the defective Pinnacle device, Plaintiff suffered from metallosis, leaking of cobalt and chromium ion into his blood stream, metal-on-metal friction, and significant pain and suffering.

48. On March 4, 2015, due to the defective Pinnacle device, Plaintiff underwent revision surgery on his right hip.

49. After the revision surgery, Plaintiff has suffered other medical complications, which on information and belief, are related to the cobalt and chromium ion leaking into his bloodstream.

V. CLAIMS FOR RELIEF

A. Strict Liability – Design Defect

50. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs, and further alleges as follows:

51. Defendants DePuy and Johnson & Johnson are in the business of designing, manufacturing, and selling hip implant devices.

52. Defendants DePuy and Johnson & Johnson made every and all decisions regarding, but not limited to, the design, manufacture, testing, labeling, sterilization, packaging, marketing, advertising, selling, supplying, distribution, and warning of the Pinnacle devices.

53. DePuy and Johnson & Johnson distributed the Pinnacle devices implanted in Plaintiff into the stream of commerce.

54. The Pinnacle device in question was unreasonably dangerous when it left the custody, control and possession of Defendants—one or all of them.

55. The Pinnacle device was designed and manufactured in a manner that is defective and unreasonably dangerous to the consumers for the purpose for which it is designed. Specifically, but not limited to, the Pinnacle device is known to shed metal debris into patients' tissue and bone.

56. The Pinnacle device in question was unreasonably dangerous based on the leaking of the cobalt and chromium when sold by Defendants to Plaintiff's doctor and thereafter implanted into Plaintiff by his doctor.

57. Upon information and belief, Defendants—one or all of them—as of the date their agent sold the product in question to Plaintiff's doctor, knew or reasonably should have known of the extremely high number of Pinnacle devices that were leaking chromium and cobalt and were not functioning properly.

58. The Pinnacle hip implant device reached Plaintiff without substantial change in the condition in which it was sold.

59. The hip implant device was used in the manner for which it was intended.

60. Plaintiff was not aware of, nor could he have reasonably known of, or discovered, the dangerous nature of the hip implant device until well after they were implanted in him, causing him subsequent injuries.

61. As a direct and proximate cause of DePuy and Johnson & Johnson placing the Pinnacle implants into the stream of commerce, Plaintiff has suffered and will suffer injuries and significant damages, including, but not limited to physical injury, medical complications, pain and suffering, mental and emotional anguish, fear of future injuries,

loss of enjoyment of life, significant medical expenses, future medical expenses, and other specific and general damages.

B. Strict Liability – Failure to Warn

62. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs, and further alleges as follows:

63. Defendants DePuy and Johnson & Johnson are in the business of designing, manufacturing, and selling hip implant devices.

64. Defendants DePuy and Johnson & Johnson knew or should have known that the Pinnacle device would be surgically implanted into consumers in the same manner in which the Pinnacle device was implanted in Plaintiff.

65. The Pinnacle devices placed into the stream of commerce by Defendants DePuy and Johnson & Johnson were defective in that they were not accompanied by an adequate warning, as Defendants knew or should have known that the Pinnacle devices were prone to early failure, rapidly degraded, caused the release of toxins in patients, introduced metallosis resulting in the necessity of revision surgeries, and were likely to cause severe pain, suffering, debilitating physical conditions, and permanent injury. Defendants failed to provide adequate warnings of these risks to Plaintiff and other consumers of the Pinnacle devices, or to Plaintiff's doctor or other physicians.

66. As a direct and proximate cause of DePuy's and Johnson & Johnson's failure to give adequate warning and failing to warn of the significant risks associated with the Pinnacle device, Plaintiff has suffered and will suffer injuries and significant damages, including, but not limited to physical injury, medical complications, pain and suffering,

mental and emotional anguish, fear of future injuries, loss of enjoyment of life, significant medical expenses, future medical expenses, and other specific and general damages.

C. Negligence

67. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs, and further alleges as follows:

68. Defendants had a duty to exercise reasonable care in the design, manufacture, marketing, selling, and distributing of the Pinnacle devices, including, but not limited to, ensuring that the devices did not pose risks and dangers of adverse events to those implanted with the devices.

69. Defendants breached their duty of reasonable care by designing, manufacturing, marketing, selling, distributing, and failing to adequately warn patients and physicians of the risks and dangers associated with the use of metal-on-metal devices.

70. Despite the fact that Defendants knew or should have known of adverse risks, such as early failure and the release of metal debris into patients' bodies, Defendants continued to manufacture, market, sell, and distribute the Pinnacle devices.

71. As a direct and proximate cause of Defendants' negligence in the design, manufacture, marketing, selling, and distribution of the Pinnacle devices, Plaintiff has suffered and will suffer injuries and significant damages, including, but not limited to physical injury, medical complications, pain and suffering, mental and emotional

anguish, fear of future injuries, loss of enjoyment of life, significant medical expenses, future medical expenses, and other specific and general damages.

D. Breach of Express Warranty

72. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs, and further alleges as follows:

73. Upon information and belief, Defendants expressly warranted to Plaintiff and Dr. Nadaud, by and through Defendants or their authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, medical patients, and the general public that Pinnacle devices were safe, fit, and proper for their intended use as hip implant devices.

74. Upon information and belief, in his decision to implant the Pinnacle device into Plaintiff, Dr. Nadaud relied on the skill, judgement, representations, and warranties of Defendants.

75. The express warranties Defendants made were false in that the Pinnacle device was not safe, fit, or proper for its intended use.

76. The Pinnacle device did not conform to the Defendants' express and implied warranties and representations because the device failed, causing injury, pain and suffering, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

77. As a direct and proximate cause of Defendants' breach of their express and implies warranties regarding the safety and effectiveness of the Pinnacle device, Plaintiff has suffered and will suffer injuries and significant damages, including, but not

limited to physical injury, medical complications, pain and suffering, mental and emotional anguish, fear of future injuries, loss of enjoyment of life, significant medical expenses, future medical expenses, and other specific and general damages.

E. Breach of Implied Warranty of Merchantability

78. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs, and further alleges as follows:

79. Defendants designed, manufactured, tested, marketed, and distributed into the stream of commerce the Pinnacle devices, including the one implanted into Plaintiff.

80. Defendants knew the use for which the Pinnacle devices were intended and impliedly warranted the devices to be of merchantable quality and safe for such use.

81. Plaintiff and Dr. Nadaud reasonably relied upon the skill and judgment of Defendants as to whether the Pinnacle devices were of merchantable quality and safe for its intended use.

82. Contrary to Defendants' implied warranties, the Pinnacle device was not of merchantable quality or safe for its intended use because it was unreasonably dangerous as described above.

83. As a direct and proximate cause of Defendants' breach of the implied warranty of merchantability regarding the safety and effectiveness of the Pinnacle device, Plaintiff has suffered and will suffer injuries and significant damages, including, but not limited to physical injury, medical complications, pain and suffering, mental and emotional anguish, fear of future injuries, loss of enjoyment of life, significant medical expenses, future medical expenses, and other specific and general damages.

F. Breach of Implied Warranty of Fitness

84. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs, and further alleges as follows:

85. Defendants DePuy and Johnson & Johnson designed, manufactured, tested, marketed, distributed, and sold the Pinnacle device into the stream of commerce.

86. Defendants knew or should have known the particular purpose for which the Pinnacle device was required by Plaintiff and that Plaintiff was relying on Defendants' skill and judgment to select and furnish a suitable, safe, and effective Pinnacle device.

87. Defendants failed to select and supply a Pinnacle device that was fit for the particular purpose for which Plaintiff required such hip product, which was completely foreseeable to all Defendants.

88. As a direct and proximate cause of Defendants' wrongful conduct, Plaintiff has suffered and will suffer injuries and significant damages, including, but not limited to physical injury, medical complications, pain and suffering, mental and emotional anguish, fear of future injuries, loss of enjoyment of life, significant medical expenses, future medical expenses, and other specific and general damages.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff respectfully requests this Honorable Court grant him the following relief:

1. Let process issue, requiring these Defendants to Answer this Complaint;

2. Empanel a jury to try all issues in dispute;

3. Award Plaintiff damages in the amount of $1,250,000.00;

4. Award Plaintiff pre-judgment interest on all sum certain economic losses;

5. Award Plaintiff discretionary costs;

6. Award Plaintiff any further or general relief to which he may be entitled.

RESPECTFULLY SUBMITTED, THIS the 4th day of September, 2015.

/ Darren V. Berg_____
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